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No. 06-830

Supreme Court, U.S.
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IN THE

# Supreme Court of the United States

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BETTY JOBLOVE, *et al.*,
*Petitioners*,

v.

BARR LABORATORIES, INC., *et al.*,
*Respondents*.

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**On Petition for Writ of Certiorari to the United States Court of Appeals for the Second Circuit**

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## BRIEF IN OPPOSITION

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GEORGE C. LOMBARDI
LINDA T. COBERLY
MAUREEN L. RURKA
KEVIN E. WARNER
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
(312) 558-5600

*Attorneys for Respondent Barr Laboratories, Inc.*

ARTHUR F. GOLDEN
*Counsel of Record*
JOEL M. COHEN
CHARLES S. DUGGAN
DOUGLAS K. YATTER
DAVIS POLK & WARDWELL
450 Lexington Avenue
New York, New York 10017
(212) 450-4388

*Attorneys for Respondents AstraZeneca Pharmaceuticals LP, Zeneca Inc. and AstraZeneca PLC*

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

## QUESTION PRESENTED

Whether the Sherman Act prohibits a settlement of drug patent litigation that includes a payment to the alleged infringer and an agreement by the alleged infringer not to manufacture the patented drug in exchange for a supply of the drug and the right to sell it in competition with the patent holder, where there is no allegation that the settlement was not a resolution of a legitimate patent dispute or that the agreement exceeded the bounds of the exclusivity conferred by the patent.

## STATEMENT PURSUANT TO SUPREME COURT RULE 29.6

The parent corporation of respondent Barr Laboratories, Inc. is Barr Pharmaceuticals, Inc., which is the only publicly held company that owns 10% or more of Barr Laboratories, Inc.'s stock.

Respondent AstraZeneca PLC has no parent corporation, and there is no publicly held company that owns 10% or more of its stock.

The parent corporation of respondent Zeneca Inc. is Zeneca Holdings Inc., and its ultimate parent corporation is respondent AstraZeneca PLC. Apart from respondent AstraZeneca PLC (through its indirect holding), there is no publicly held company that owns 10% or more of the stock of Zeneca Inc. or Zeneca Holdings Inc.

Respondent AstraZeneca Pharmaceuticals LP is a limited partnership whose general partner is AstraZeneca AB. The ultimate parent corporation of AstraZeneca AB is respondent AstraZeneca PLC. Apart from respondent AstraZeneca PLC (through its indirect holding), there is no publicly held company that owns 10% or more of the stock of AstraZeneca AB or that has any ownership interest in AstraZeneca Pharmaceuticals LP.

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**On Petition for Writ of Certiorari to the United States Court of Appeals for the Second Circuit**

## BRIEF IN OPPOSITION

None of the reasons advanced by petitioners supports this Court's review of the court of appeals' decision. There is no conflict in the courts of appeals as to when settlements of genuine patent disputes may violate the Sherman Act. Indeed, within the past year, the Solicitor General concluded that no conflict exists that would warrant this Court's review of this issue, based on the same body of case law that exists today. *See* Brief for the United States as Amicus Curiae at 16-20, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273) ("U.S. *Schering* Br.") ("There Is No Circuit Split Justifying This Court's Review"). Nor is there any "uncertainty," much less "confusion," Pet. 15-17, about the propriety of settling lawsuits over drug patents on terms that include consideration to generic drug manufacturers.

The court of appeals rightly rejected petitioners' contention that respondents violated the Sherman Act by settling, instead of litigating to the end, a legitimate dispute between them over the validity of the patent for the drug tamoxifen. That ruling is entirely consistent with this Court's precedents. "Where there are legitimately conflicting [patent] claims * * *, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act," *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931), provided that such agreements do not constrain trade beyond "the limits of the patent monopoly," *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963). Following those principles, the court below correctly held that petitioners had failed to state a claim that respondents' settlement violated the Sherman Act, because petitioners had alleged no facts that, if proved true, would establish that the defense of the patent (and, by extension, the settlement) was not legitimate or that the settlement's terms extended beyond the scope of the patent. The petition provides no reason to question the correctness of that decision. Dismissal of the complaint was appropriate on the facts alleged, and this case accordingly provides no basis to consider "under what circumstances" a settlement might violate the Sherman Act, *cf.* Pet. *i.*

The Second Circuit properly concluded that the legality of respondents' settlement under the Sherman Act does not turn on post-hoc conjectures that, but for the settlement, respondents' patent lawsuit would have resulted in the invalidation of the patent. The court rightly reasoned that, if petitioners' arguments were accepted, virtually every settlement of patent litigation would potentially give rise to an antitrust claim—with liability hinging on the same uncertain patent question that the settlement sought to compromise, but now with the threat of trebled damages to third parties. The court also correctly decided, along with other courts, that the payment of consideration to settle a patent challenge, by itself, is not inherently improper (as petitioners conceded below, Pet. App.

36a), nor even indicative of a weak patent, *id.* at 47a, as the Solicitor General has also noted, U.S. *Schering* Br. at 10 (explaining that, in drug patent cases, such "payments are more likely, even when the patentee's legal claims are strong"). Petitioners' novel arguments find no support in this Court's antitrust or patent precedents, and it is altogether unsurprising that they were rejected by the courts below.

Apart from these considerations, this case is a poor vehicle for considering the requirements for pleading that a drug patent settlement violated the Sherman Act. As the court below noted, the "particular factual circumstances" of this case "are unlikely to recur." Pet. App. 2a. Appellate panels will no longer vacate a district court judgment as part of a settlement, as happened here. Moreover, respondent AstraZeneca successfully defended its patent in two fully litigated actions after the challenged settlement, a case-specific feature of this lawsuit that the petition all but ignores. In addition, the statutory regime that governs drug patent challenges, which the petition discusses at length, Pet. 2-3, 24-27, has been amended since respondents' settlement in 1993. And finally, the only live controversy at this point is whether petitioners have stated valid state law claims, although those state law claims presumably are governed by the same standards that govern claims under the Sherman Act, including federal patent law principles. As indirect purchasers, petitioners sought only declaratory and injunctive relief under the Sherman Act, which they can no longer obtain because respondents' agreement terminated with the expiration of the patent in 2002. These considerations all weigh against review of this case.

## STATEMENT

1. In 1985, respondent AstraZeneca obtained a patent for the cancer drug tamoxifen ("the '516 patent"). Also that year, the Food and Drug Administration approved AstraZeneca's New Drug Application to begin selling the drug. Four

months later, respondent Barr Laboratories, Inc. ("Barr") filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market a generic version of tamoxifen upon the expiration of AstraZeneca's patent.[1]

In 1987, Barr amended its ANDA to include a certification that AstraZeneca's '516 patent "[wa]s invalid or w[ould] not be infringed" by Barr's generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (1988). At the time, the filer of such a certification (a "paragraph IV certification") was entitled under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355 *et seq.*) (the "Hatch-Waxman Act"), to a 180-day period of market exclusivity for its generic drug, running from the date it began to market its drug or, if earlier, the date a court declared the patent invalid or not infringed by the drug. 21 U.S.C. § 355(j)(4)(B)(iv) (1988) (amended 1997 and 2003). The filing of a paragraph IV certification is a technical act of infringement, 35 U.S.C. § 271(e)(2)(A), and the filing of an infringement action by the patent holder within a specific period of time automatically stays the FDA from approving the filer's ANDA for thirty months, absent court action. 21 U.S.C. § 355(j)(4)(B)(iii).

In response to Barr's paragraph IV filing, AstraZeneca sued Barr for patent infringement, and Barr defended on the ground that the patent was invalid. In May 1992, after a bench trial, the district court ruled that the '516 patent was invalid and unenforceable as a result of a purported failure by AstraZeneca to disclose certain mouse test data while prosecuting the patent. *Imperial Chem. Indus., PLC v. Barr Labs.*, 795 F. Supp. 619, 627 (S.D.N.Y. 1992). AstraZeneca appealed the district court's ruling to the Federal Circuit.

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[1] Respondents AstraZeneca PLC, AstraZeneca Pharmaceuticals LP and Zeneca Inc. are referred to herein as "AstraZeneca."

2. In March 1993, while the appeal was pending, respondents settled the case. Barr surrendered its claims that the '516 patent was invalid in exchange for the right to begin selling a competing tamoxifen product under a distributorship agreement with AstraZeneca, well prior to the expiration of the patent. Barr also received a $21 million payment, and AstraZeneca also agreed to pay $45 million over ten years to Barr's intended supplier. The settlement was conditioned on the vacatur of the district court judgment and dismissal of the action. The Federal Circuit, in keeping with its practice at the time, granted respondents' joint motion for vacatur, *Imperial Chem. Indus., PLC v. Heumann Pharma GmbH*, 991 F.2d 811 (table), 1993 WL 118931, at *1 (1993), and after remand the district court dismissed the case. Barr thereafter began to sell its competing tamoxifen product.

3. After settling the lawsuit, AstraZeneca successfully defended its '516 patent against other generic drug manufacturers. In 1994, Novopharm Ltd. filed a paragraph IV certification challenging the '516 patent, and AstraZeneca sued for infringement. After trial on the merits, a federal district court in Maryland upheld the validity of the '516 patent, expressly rejecting the arguments for invalidity that had been accepted by the district court in the *Barr* case. *See* Tr. of Oral Op., *Zeneca Ltd. v. Novopharm Ltd.*, Civ. No. HAR 93-1627, at 1658-62, 1680-82 (D. Md. Apr. 26, 1996). The court's judgment was affirmed by the Federal Circuit. *Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144 (table), 1997 WL 168318 (1997).

In 1996, AstraZeneca brought separate infringement lawsuits against Mylan Pharmaceuticals and Pharmachemie B.V., after they each filed paragraph IV certifications. In the lawsuit against Pharmachemie, a federal district court in Massachusetts specifically rejected an argument by Pharmachemie that respondents' settlement of the *Barr* lawsuit had been improper, *see Zeneca Ltd. v. Pharmachemie B.V.*, 37 F.

Supp. 2d 85, 86, 93 (D. Mass. 1999), and after trial entered judgment for AstraZeneca on the validity of the '516 patent, *Zeneca Ltd. v. Pharmachemie B.V.*, Civ. No. 96-12413-RCL (D. Mass. Sept. 14, 2000). That judgment was not appealed. Shortly thereafter, Mylan abandoned its challenge and consented to an order that prevented it from marketing generic tamoxifen until after the expiration of the '516 patent. *See AstraZeneca UK Ltd v. Mylan Pharms., Inc.*, Civ. Nos. 00-2239, 96-335 (W.D. Pa. Nov. 30, 2000).

4. Petitioners are persons who allegedly indirectly purchased or paid for tamoxifen. Beginning in 2000, they filed thirty purported class actions in federal and state courts across the country, which were consolidated for pretrial proceedings in the federal district court for the Eastern District of New York. *In re Tamoxifen Citrate Antitrust Litig.*, 196 F. Supp. 2d 1371 (J.P.M.L. 2001). Following the district court's denial of certain petitioners' motions to remand, all petitioners were joined as plaintiffs in a single consolidated action seeking declaratory and injunctive relief under the Sherman and Clayton Acts, 15 U.S.C. §§ 1, 2, 26, and monetary remedies under state common law and various state antitrust, unfair competition and consumer protection statutes.

The complaint alleged that petitioners had paid excessive prices for tamoxifen as a result of respondents' settlement. Petitioners alleged that the benefits to Barr under the settlement exceeded the profits Barr would have earned selling generic tamoxifen had it prevailed in the lawsuit. Compl. ¶ 45. Petitioners asserted that, had the *Barr* lawsuit not been settled, "the Federal Circuit and/or the Supreme Court" would have affirmed the district court's judgment that the patent was invalid, *id.* ¶ 54, an outcome that supposedly would have

invited open competition by generic manufacturers and resulted in lower tamoxifen prices, *id.*[2]

The district court dismissed the complaint. Reviewing this Court's precedents, it observed that parties may settle patent litigation so long as they do not combine in bad faith against other competitors, Pet. App. 83a-84a, and held that petitioners had alleged no basis for inferring that respondents' settlement had been made in bad faith, *id.* at 97a-98a. The court also held that the loss claimed by petitioners was not compensable "antitrust injury," because the lack of additional generic competition was attributable, not to the settlement, but to the generic manufacturers' failures to prove that the '516 patent was invalid. *Id.* at 98a-102a.

5. The court of appeals affirmed. As an initial matter, it denied respondents' motion to transfer the case to the Federal Circuit, which under 28 U.S.C. § 1295(a)(1) has exclusive jurisdiction over appeals of cases that "arise under" federal patent law. The court noted that under *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800, 807 (1988), a case does not "arise under" patent law "as long as there is at least one alternative theory supporting the claim that does not rely on patent law." Pet. App. 23a. Applying that principle, the court concluded that the Federal Circuit did not have exclusive jurisdiction over the appeal. *Id.* at 24a.

On the merits, the court of appeals held that petitioners had failed to state an antitrust claim. The court noted that the settlement of "legitimately conflicting [patent] claims * * * is not precluded by the [Sherman] Act." *Id.* at 30a (quoting *Standard Oil*, 283 U.S. at 171). The allegation that respondents settled their lawsuit after the district court had declared

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[2] The complaint also asserted that respondents agreed "to preserve Barr's claim to the [180-day] exclusivity period so that it could be strategically deployed * * * to block any potential competitor from the market." *Id.* ¶ 57.

the patent invalid was, it held, insufficient to state an antitrust claim. *Id.* at 35a. The court denied that it could "guess with any degree of assurance what the Federal Circuit would have done" in the appeal, *id.* at 32a, noting in particular AstraZeneca's later successes defending the patent, *id.* at 34a.

The court also held that petitioners did not state a claim by alleging that the consideration paid to Barr under the settlement exceeded the supposed profits Barr would have made selling generic tamoxifen had it won on appeal. *Id.* at 36a. The court noted that, in litigation under the Hatch-Waxman regime, generic manufacturers "might well have the whip hand" in extracting substantial payments from patent holders, even when the patent holder is confident in the strength of its patent. *Id.* at 45a. To state a claim that a settlement of patent litigation violated the Sherman Act, the court held, a plaintiff must allege that "the exclusionary effects of the agreement exceeded the scope of the patent's protection," or that the patent had been obtained by fraud, or that the defense of the patent had been "objectively baseless." *Id.* at 51a-52a (citations and internal quotations omitted).

The court noted that petitioners had not alleged fraud or asserted that AstraZeneca's defense of the patent was baseless, *id.* at 52a-53a, and it held that the complaint did not support a claim that the settlement exceeded the scope of the patent, in contrast to the agreement criticized by the Sixth Circuit in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (2003), *cert. denied*, 543 U.S. 939 (2004), *see* Pet. App. 54a. Nor did respondents' settlement prevent other generic manufacturers from obtaining FDA approval for their competing drugs, unlike certain "interim" agreements in other cases that did not resolve the litigation but instead "prolonged it by providing incentives to the defendant generic manufacturers not to pursue the litigation avidly." *Id.* at 55a-56a (distinguishing *Cardizem*, 332 F.3d at 907, and *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1300 (11th

Cir. 2003), *cert. denied*, 543 U.S. 939 (2004)). The court also noted that, by licensing Barr to distribute a competing tamoxifen product at a reduced price, the settlement introduced competition that would not have existed had AstraZeneca prevailed on appeal. *See id.* at 57a-58a.[3]

The dissenting judge argued that the validity of drug patent settlements should turn on their "reasonableness" in view of "the strength of the patent" at the time of the settlement, the amount of the payment to the generic challenger, the amount the generic challenger would have earned during the Hatch-Waxman exclusivity period and any ancillary anticompetitive effects of the agreement. *Id.* at 126a.

## REASONS FOR DENYING THE PETITION

The petition advances no reason that warrants review of the decision below. There is no conflict in the courts of appeals, and the Second Circuit properly applied this Court's precedents in rejecting petitioners' novel antitrust claims. In addition, there are several reasons why this case, with its factual background that is unlikely ever to recur, is a poor vehicle for considering the standards for pleading that a drug patent settlement violated the Sherman Act.

### I. THERE IS NO CONFLICT IN THE COURTS OF APPEALS

There is no conflict in the decisions of the circuit courts that have assessed antitrust challenges to agreements arising from drug patent litigation under the Hatch-Waxman Act. None of the three circuits that petitioners assert are in conflict

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[3] The court also held that petitioners had failed to state an antitrust claim by alleging that respondents had agreed that Barr would seek to preclude competition by other generic manufacturers. Pet. App. 63a-67a. That claim, the court held, was so lacking in any alleged factual predicate as to fall outside "the realm of plausible possibilities." *Id.* at 63a.

has permitted claims to proceed where the challenged agreements did not exceed the scope of the patents at issue. Nor has any of the three circuits considered the amount of the payment made to the generic challenger as a sufficient basis in itself for Sherman Act liability. Any variance in outcomes in the courts of appeals' decisions is attributable, not to their having adopted conflicting approaches, but to the different settlement terms under examination. In short, the conflicts claimed by petitioners do not exist. Indeed, less than a year ago, the Solicitor General explained to this Court, in a case raising similar issues, that "There Is No Circuit Split Justifying This Court's Review." Brief for the United States as Amicus Curiae at 16-20, *FTC v. Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (No. 05-273) ("U.S. *Schering* Br."). That view was based on the same body of appellate case law as exists today, including the decision by the Second Circuit below.

There is no conflict between the Second Circuit's decision below and the Sixth Circuit's decision in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (2003), *cert. denied*, 543 U.S. 939 (2004), as the Solicitor General has previously noted, *see* U.S. *Schering* Br. at 19 (stating that the decision in this case "does not create any split with the Sixth Circuit's *Cardizem* decision"). In *Cardizem*, the Sixth Circuit held that an "interim" agreement, under which the patent holder paid a generic competitor not to sell a competing drug until a final resolution of patent litigation, constituted a "naked, horizontal restraint of trade" that was per se unlawful. 332 F.3d at 911. But the agreement in *Cardizem* extended to drugs "not at issue in the pending litigation," including "noninfringing" versions of the patented drug. *Id.* at 908 n.13 (citations and internal quotations omitted). In other words, it "involved payments to exclude drugs that did *not* fall within the scope of the patent alleged to be infringed." U.S. *Schering* Br. at 17 (emphasis in original).

The Second Circuit rightly distinguished respondents' settlement from the agreement in *Cardizem*. It noted that respondents' settlement, "unlike the agreement * * * in *Cardizem*," did not "restrain[] the introduction or marketing of unrelated or non-infringing products." Pet. App. 53a-54a. Nothing in the Second Circuit's decision suggests any disagreement with the Sixth Circuit's conclusion in *Cardizem*. Indeed, the Second Circuit made clear that it regarded the *Cardizem* agreement as precisely the kind of arrangement that *would* violate the Sherman Act. *Id.* at 53a-55a.[4]

Nor is there any conflict between *Cardizem* and the Eleventh Circuit's decision in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (2003), *cert. denied*, 543 U.S. 939 (2004). In *Valley Drug*, the Eleventh Circuit reversed a district court ruling that certain "interim" reverse payment agreements were per se antitrust violations. The Eleventh Circuit held that antitrust liability could not be imposed on the basis that the patent was later invalidated, *id.* at 1306-07, or that the patent holder had made payments to the challenger, *id.* at 1309-11. The legality of the agreement, the court held, turned on whether its exclusionary effects "are within the scope of the exclusionary potential of the patent." *Id.* at 1311. The court in *Valley Drug* therefore remanded for the district court to determine the scope of "the protection afforded by the patents and the relevant law" and to consider "the extent to which the [a]greements reflect a reasonable implementation of the[m]." *Id.* at 1312. Any agreement outside the scope of the patent, it held, would be subject to the

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[4] The Second Circuit also noted that the *Cardizem* agreement was designed to block other potential generic competitors from coming to market, in part by delaying the resolution of the parties' patent litigation. *Id.* at 56a; *see also Cardizem*, 332 F.3d at 907-08 & n.12. Here, by contrast, as the Second Circuit noted, respondents' agreement did not constrain third parties. *Id.* at 55a-56a.

standard antitrust analysis applicable to agreements between competitors. *Id.*

That holding is entirely consistent with *Cardizem* and with the Second Circuit's decision in this case. Under *Valley Drug*, applying standard antitrust principles, a horizontal restraint on competition that exceeded the scope of the patent would be illegal, *see* 344 F.3d at 1312-13, just as it was in *Cardizem*. And in the decision below, the Second Circuit expressly approved the Eleventh Circuit's analysis in *Valley Drug* and its later decision applying the same standard in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (2005), *cert. denied*, 126 S. Ct. 2929 (2006). Indeed, the Second Circuit's core holding—that "the question is whether the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection'"—is adopted from the Eleventh Circuit's decision in *Schering-Plough*. Pet. App. 53a (quoting 402 F.3d at 1076); *see also* U.S. *Schering* Br. at 19 (noting the Second Circuit's endorsement of the Eleventh Circuit's approach).[5]

Nor do the Second Circuit and the Eleventh Circuit have conflicting views on the significance of the amount of consideration paid to generic manufacturers in settling patent disputes. Nothing in the decision below conflicts with *Valley Drug*'s observation that large payments "might be evidence supporting a claim that the patentee knew that the patent was procured by fraud, or knew that the patent was invalid, or that

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[5] Although the *Valley Drug* court read *Cardizem* as suggesting that even agreements not to market infringing products might be per se illegal, it also recognized that such a rule was not necessary to the decision in *Cardizem*, since the agreement there exceeded the scope of the patent. *See Valley Drug*, 344 F.3d at 1311 n.26. As the Solicitor General has noted, "it is far from clear that the per se rule employed [in *Cardizem*] extends beyond the unique circumstances of that case." U.S. *Schering* Br. at 17; *see also* Brief for the United States as Amicus Curiae at 11, *Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779) (stating that *Cardizem* and *Valley Drug* "do not present a square conflict").

there was no objective basis to believe the patent was valid." 344 F.3d at 1310 n.22; *cf.* Pet. 13-14. The Second Circuit never suggested that the size of a payment would be irrelevant to showing fraud or bad faith. It held, rather, that an allegation of a large payment was not in itself sufficient to state a claim that a patent enforcement action was brought and settled in bad faith. *See* Pet. App. 36a-48a. The Eleventh Circuit reached the same basic conclusion in *Valley Drug*. It could not conclude, it held, "merely from the size of the payments, that there were no genuine disputes over the validity of the patent." 344 F.3d at 1310. Rather, it tied the significance of large payments to the presence of fraud, bad faith or objective unreasonableness, *id.* at 1310 n.22, the same elements that the Second Circuit stated would support a Sherman Act claim, Pet. App. 51a-52a. On these points, as otherwise, the two circuits agree. There is no conflict to be resolved by this Court.[6]

## II. THE COURT OF APPEALS CORRECTLY HELD THAT PLAINTIFFS' ALLEGATIONS FAILED TO STATE A CLAIM UNDER THE SHERMAN ACT

The Second Circuit correctly rejected petitioners' novel theory that respondents' settlement was unlawful because it brought to an end litigation that purportedly would have

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[6] Petitioners incorrectly argue that *Valley Drug* would have treated respondents' agreement as per se illegal because it was reached after a judgment that the patent was invalid, citing *Valley Drug*'s statement that it was not per se unlawful for generic manufacturers to agree not to sell infringing products at a time when "no court had declared [the] patent invalid." Pet. 13 (quoting 344 F.3d at 1306 & n.18). That statement does not necessarily imply that it *would* be unlawful to reach such an agreement while a district court judgment of invalidity is being appealed. Moreover, even if it did, the possibility of a disagreement between the courts of appeals on that narrow point would not merit review, because it is unlikely that future cases will feature settlements made after a district court judgment of invalidity. *See infra* at 26-27.

resulted in the invalidation of the '516 patent. It also correctly determined that petitioners had not stated a claim simply by alleging that the settlement payments to Barr exceeded the profits that Barr allegedly would have earned selling generic tamoxifen. The Second Circuit's analysis of these issues was entirely consistent with established principles of patent and antitrust law, and none of the arguments advanced by petitioners justifies its review by this Court.

### A. Agreements To Settle Legitimate Patent Disputes Do Not Violate the Sherman Act

There is no question that "[w]here there are legitimately conflicting [patent] claims * * *, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act." *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931). Settlements of patent disputes serve the basic purposes of patent law by resolving costly litigation that might otherwise discourage innovation. Pet. App. 30a-31a; *see also Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1369 (Fed. Cir. 2001) ("[S]ettlement of [patent] litigation is * * * strongly favored by the law."). Nor is there anything about settlements of drug patent disputes that would alter this general principle. Petitioners do not contend that all drug patent settlements, or even all so-called "reverse payment" settlements, are unlawful. Pet. App. 36a, 41a.

It is also well established that "the essence of a patent grant is the right to exclude others from profiting by the patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). For this reason, it has long been recognized that a patent holder, in granting a license, may enter into agreements restricting competition in the patented product that might be unlawful under the Sherman Act absent the statutory right against infringement that the patent confers. *See, e.g., Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135-36 (1969); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 455-56 (1940); *Gen. Talking Pictures*

*Corp. v. Western Elec. Co.*, 304 U.S. 175, 181 (1938); *see also Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) ("The patent laws * * * are *in pari materia* with the antitrust laws and modify them *pro tanto*."). Such an agreement, without more, does not raise antitrust concerns unless it has the effect of restraining trade or erecting barriers to entry beyond the scope of the patent. *See, e.g., United States v. Line Material Co.*, 333 U.S. 287, 308 (1948); *United States v. Masonite Corp.*, 316 U.S. 265, 278-79 (1942). Nor do petitioners seek review of the court of appeals' case-specific determination that respondents' settlement did not exceed the scope of the '516 patent. *See* Pet. App. 53a-59a.

Where, as here, an agreement falls within the scope of a patent, a claim that the agreement violated the Sherman Act must be supported by factual allegations that the patent was obtained by fraud or had been enforced in bad faith. In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 175-77 (1965), this Court held that a party that enforces a patent knowing that it was fraudulently obtained, and thus invalid, may be sued for violating the Sherman Act. The Court's opinion made clear, however, that the essential predicate for such a claim was the allegation that the patent had been "procured by intentional fraud," not that the patent was later held to be invalid. *Id.* at 176; *see also id.* at 177 (stating that the patent holder's "good faith would furnish a complete defense"). In keeping with these principles, the courts of appeals have recognized that the bad faith or baseless enforcement of patents may give rise to antitrust violations. *See, e.g., Valley Drug*, 344 F.3d at 1310 n.22; *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068-71 (Fed. Cir. 1998) (citing *Walker Process* and *Prof'l Real Estate Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993)).

The court of appeals' holding that petitioners failed to state a claim because they did not allege that the '516 patent

had been fraudulently obtained or enforced in bad faith was entirely consistent with these patent and antitrust precedents. Petitioners' assertion that the court deemed patent settlements "per se legal," Pet. 12, both mischaracterizes its ruling and ignores its precedential support in the decisions of this Court and other courts of appeals. Their argument that the court of appeals "imported" part of its standard from cases regarding protected First Amendment activity, *id.* at 19-20, fails to take account of the well established antitrust doctrines reflected in those precedents. Petitioners have cited no contrary authority of this Court (or any other court) that calls into question the court of appeals' reasoning below. [7]

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[7] Petitioners cite several cases where antitrust claims proceeded beyond the pleadings, Pet. 18, but in each of them, the factual allegations differed from those here. In *Cardizem*, 332 F.3d at 907-08 & nn.12-13, the agreement limited non-infringing products and prevented other generics from entering the market. *See also supra* at 11 n.4. Similar allegations were made in *Andrx Pharmaceuticals, Inc. v. Elan Corp., PLC*, 421 F.3d 1227, 1231, 1235 (11th Cir. 2005) (noting that agreement prevented other generics from entering the market), and in *In re Terazosin Hydrochloride Antitrust Litigation*, 352 F. Supp. 2d 1279, 1314-15 & nn.35-36 (S.D. Fla. 2005) (analogizing agreement to the one at issue in *Cardizem* and distinguishing it from the one here). In *In re Buspirone Patent Litigation*, 185 F. Supp. 2d 363, 366, 378 (S.D.N.Y. 2002), the complaint alleged that the "settlement was a sham" that the parties made in bad faith. And in *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International*, 256 F.3d 799, 803-05, 810, 819 (D.C. Cir. 2001), the court addressed a claim by a competitor that it had been prevented from entering the market as a result of the same agreement at issue in *Cardizem*. Although the district court in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* denied a motion to dismiss, 261 F. Supp. 2d 188, 230 (E.D.N.Y. 2003), it later granted summary judgment to the defendants once it became clear (as it was here on the face of the complaint) that the agreements had no anticompetitive effect beyond the scope of the patent, 363 F. Supp. 2d 514, 540-41 (E.D.N.Y. 2005).

### B. Petitioners Have Not Stated a Sherman Act Claim by Alleging that the Patent Had Been Declared by the District Court, or Could Be Shown by Petitioners, To Be Invalid

As has been the case throughout this lawsuit, petitioners do not clearly state the theory of antitrust liability that purportedly justifies their claim. They appear to argue, at least in part, that they have stated a Sherman Act claim by alleging that respondents agreed as part of their settlement to the vacatur of the district court's decision that the '516 patent was invalid. *See, e.g.*, Pet. 4, 10-11, 20-21, 23. But insofar as they rely on that allegation, their claim rests on facts that may well be unique to this lawsuit. As discussed below, *see infra* at 26-27, appellate courts have long since ceased to vacate district court judgments on the motion of settling parties. Accordingly, even if the vacatur of the initial judgment supported petitioners' Sherman Act claims (and it does not), it would not be a useful expenditure of this Court's resources to pass on the validity of a claim that is unlikely to be asserted in any other lawsuit.[8]

In any event, on its merits, petitioners' claim suffers from the inescapably conjectural nature of its core proposition that, but for the settlement, respondents' patent dispute would ultimately have been won by Barr. The court of appeals rightly concluded that courts are poorly suited to such speculative investigations into their own workings. Pet. App. 34a (embracing "the general rule that we will ordinarily refrain from guessing what a court will hold or would have held"). That determination was unquestionably correct. How petitioners' conjectural claim would be tried to a jury, as their complaint

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[8] For the same reason, petitioners' contention that the court of appeals was wrong to ascribe a presumption of validity to the '516 patent despite the vacatur of the initial district court judgment, Pet. 20-21, also provides no basis for review.

demands, is a baffling proposition. Recognizing the complexity of patent law, Congress has provided that appeals of patent judgments lie exclusively with the Federal Circuit, 28 U.S.C. § 1295(a)(1). And yet petitioners propose to put to a jury the question of how a panel of that specialized court would have decided AstraZeneca's appeal.

Petitioners argue that little speculation would be necessary to predict the outcome of respondents' lawsuit, in view of the initial district court judgment on the patent. Pet. 10-11. But any reliance on that initial ruling would wrongly ascribe preclusive significance to a vacated judgment, as the Federal Circuit noted in affirming AstraZeneca's successful second defense of the '516 patent, *see Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144 (table), 1997 WL 168318, at *2 (1997). Moreover, as the court of appeals noted, any inference that might be drawn from the initial patent ruling is undermined by AstraZeneca's later successes defending the '516 patent. Pet. App. 34a & n.17. The court also correctly noted the difficulty of predicting the outcomes of appeals, as reflected in the frequency with which appeals are settled. *Id.* at 33a.[9]

Petitioners also argue the more ambitious point that, when patent litigation is settled, potentially affected third parties "should have their own opportunity to show the weaknesses of the patent." Pet. 21. Apart from being subject to the same difficulties of proof noted above, that position is also contrary to the basic rule of *Walker Process* that an assertion of patent invalidity cannot by itself support a claim under the Sherman Act. Petitioners' desire to "show the weaknesses" of the

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[9] The court also noted that in 1993 patent invalidity rulings were reversed "at a relatively high rate." *Id.* at 33a n.16. *See also Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 331 n.21 (1971) (noting that "[b]ecause of the intrinsic nature of [patent validity questions], the first [court's] decision can be quite wrong, or derived from an insufficient record or presentation") (citation and internal quotations omitted).

tamoxifen patent—i.e., to demonstrate in this lawsuit that the patent was invalid—is precisely the kind of challenge that *Walker Process* made clear would not be permitted. As Justice Harlan, in a concurring opinion, took pains to explain, "a private cause of action would *not* be made out if the plaintiff * * * showed no more than invalidity of the patent * * *." 382 U.S. at 179 (emphasis in original).

Although the federal government, like an alleged infringer or licensee defending a claim by a patent holder, may challenge the validity of a patent where the government contends that the patent was used to constrain competition outside the patent's scope, *see United States v. Glaxo Group Ltd.*, 410 U.S. 52, 58-59 (1973), petitioners cannot pursue a claim on this ground. Even the government does not have a "roving commission" to "attack a patent by basing an antitrust claim on the simple assertion that the patent is invalid." *Id.* at 59 (citing *Walker Process*, 382 U.S. 172). Petitioners cite no authority for the proposition that they have such a "roving commission" or standing to challenge the validity of a patent.

Nor can petitioners avoid the rule of *Walker Process* by arguing that their claim is directed at the settlement agreement rather than the validity of the patent. Since the agreement did not exceed the scope of the '516 patent, the only way it could have had any consequence for petitioners was by protecting an otherwise invalid patent, as petitioners themselves recognized in pleading their claim, Compl. ¶ 54, and thus petitioners' challenge to the settlement is necessarily, at bottom, an attack on the validity of the patent. The court of appeals' refusal to let that claim proceed was entirely consistent with this Court's precedents.

Petitioners invoke *Standard Oil* and the concurring opinion in *Singer* as ostensibly supporting their right "to show the weaknesses of the patent," Pet. 21 (citing the dissent below, Pet. App. 120a), but neither *Standard Oil* nor *Singer* suggests that claims of patent invalidity, alone, are enough to support

an antitrust claim. To the contrary, both decisions are entirely consistent with *Walker Process* and the decision below. In *Standard Oil*, the question of patent validity was tied to claims that the challenged agreements had been made "in bad faith" and that the parties' infringement claims were "a pretext" that had been asserted "merely as a means of lending color of legality" to the parties' agreements. 283 U.S. at 180. And in *Singer*, the parties had "collu[ded] * * * to prevent prior art from coming to or being drawn to the [Patent] Office's attention," i.e., had conspired to deceive the patent office in prosecuting their patents. 374 U.S. at 199-200 (White, J., concurring). Neither case suggests that the Sherman Act supplies a claim to a private litigant who wishes to "show the weaknesses" of a patent without also demonstrating fraud or bad faith. And here, as noted already, petitioners have not alleged that the '516 patent had been obtained by fraud, that AstraZeneca's defense of the patent was not genuine or that the settlement was made in bad faith.

The court of appeals rightly recognized that patent settlements would be greatly discouraged if antitrust plaintiffs could "show the weaknesses" of a patent after a settlement. There would be little reason to settle if the resolution of one dispute opened the patent to question by third parties in a new antitrust action, this time with the threat of trebled damages. *See* Pet. App. 30a-32a, 42a, 51a n.26. Further, as the Eleventh Circuit reasoned in *Valley Drug*, "[b]y restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation." 344 F.3d at 1308. Similar considerations underlay this Court's reluctance to permit antitrust claims challenging the validity of a patent. *See Walker Process*, 382 U.S. at 179-80 (Harlan, J., concurring).

Finally, if petitioners are attempting to argue that they should be allowed to show some "weakness" in the patent short of actual invalidity, their position was raised for the first

time in their petition for rehearing below, was never discussed by the court of appeals and accordingly is not properly raised for this Court's consideration. *See Hoover v. Ronwin*, 466 U.S. 558, 574 n.25 (1984). Beyond this, petitioners have articulated no reason why the settlement of litigation challenging a weak-but-not-invalid patent is anti-competitive or should be unlawful. Nor do they describe the standard that would supposedly establish that a weak-but-not-invalid patent was "too weak" to permit settlement of a challenge to its validity. To the extent that petitioners advance such a position now, their formless claim provides no basis for granting the petition.

### C. Petitioners Have Not Stated a Sherman Act Claim by Alleging that the Settlement Payment to Barr Exceeded the Profits that Barr Would Have Made Selling Generic Tamoxifen

Petitioners argue that the dismissal of their claims was improper because AstraZeneca's payments to Barr under the settlement allegedly exceeded the profits that Barr would have earned selling generic tamoxifen had it prevailed in the patent litigation. Here again, the court of appeals correctly concluded, following other courts, that petitioners' allegation failed to support a Sherman Act claim, and petitioners have supplied no reason that would warrant review of that decision.

The crux of petitioners' argument is that the payment to Barr enabled AstraZeneca to insulate its patent from challenge. Petitioners do not argue that the payment demonstrates that AstraZeneca was defending the patent in bad faith or that the settlement was a pretext. Nor do they dispute the court of appeals' conclusion that under the Hatch-Waxman regime, even a patent holder confident in the strength of its patent might be prepared to make substantial payments to eliminate even a small risk of an adverse outcome. Pet. App. 43a-45a;

*see also Schering-Plough*, 402 F.3d at 1075; *Valley Drug*, 344 F.3d at 1309-10; U.S. *Schering* Br. at 10 (explaining that, under the Hatch-Waxman Act, payments to patent challengers "are more likely, even when the patentee's claims are strong"). Rather, petitioners argue that, because the settlement payments to Barr purportedly exceeded Barr's expected profits from selling its product, petitioners are entitled to "show the weaknesses of the patent." Pet. 21.

As already discussed, however, the Sherman Act does not authorize antitrust suits on a claim that a patent is invalid. *See supra* at 18-19. Under *Walker Process*, it makes no difference that respondents settled prior litigation testing the patent or that their settlement provided for an allegedly "excessive" payment to Barr. Only allegations of fraud or bad faith will support such a claim, and as noted, petitioners have not argued fraud or bad faith in challenging respondents' settlement.

Petitioners argue at length that payments to settle drug patent litigation are contrary to the Hatch-Waxman Act's objective of promoting challenges to drug patents. *See* Pet. 7-8, 17. But nothing in the Hatch-Waxman Act prohibits or even impedes settlement of patent litigation. Nor does it follow from the Hatch-Waxman Act's encouragement of patent litigation that patent settlements are contrary to federal policy or that consumers may challenge such settlements under the Sherman Act when they provide for payments. Notably, in 2003, at a time after the dismissal of petitioners' claims by the district court in this case, Congress required parties who settled infringement actions based on paragraph IV certifications to file copies of their settlements with the Federal Trade Commission, *see* Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("2003 Medicare Act"), Pub. L. No. 108-173, §§ 1111-18, 117 Stat. 2066 (codified at

21 U.S.C. § 355), but took no action to limit the terms of settlement.[10]

Although the point was hardly critical to the holding below, petitioners challenge the court of appeals' assessment that a settlement with the first generic manufacturer to challenge the '516 patent would prompt other generic manufacturers to challenge the patent as well. *See* Pet. 24-26 (citing Pet. App. 50a). That assessment, they argue, rested on a mistaken belief that the Hatch-Waxman Act provided incentives for other generic manufacturers to challenge the patent. The record, however, plainly bears out the court's assessment, because after Barr settled its lawsuit, three other generic manufacturers *did* file paragraph IV certifications challenging the tamoxifen patent. *See supra* at 5. Nor was the court of appeals mistaken in its understanding of the Hatch-Waxman Act as it existed at the time of the settlement.[11] But in any event, the court's assessment of the

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[10] Congress is considering legislation amending the Hatch-Waxman Act that would prohibit certain settlements of drug patent infringement suits brought pursuant to the Act. *See* S. 316, 110th Cong. § 3 (2007) (proposing to prohibit "resolv[ing] or settl[ing] a patent infringement claim" on terms that would provide the paragraph IV filer "anything of value" apart from "the right to market [its purportedly infringing product] prior to the expiration of the patent").

[11] The paragraph IV filers who challenged the tamoxifen patent after respondents settled their lawsuit clearly perceived a possibility to benefit from the statutory 180-day exclusivity period after Barr withdrew its application. *See Mylan Pharms., Inc. v. Henney*, 94 F. Supp. 2d 36, 44 (D.D.C. 2000) (noting that Mylan sought the 180-day exclusivity period after Barr withdrew its paragraph IV certification). At the time, it was possible that the statute would be construed to grant subsequent filers exclusivity in certain circumstances. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1064 n.4 (D.C. Cir. 1998) (observing that "the statute might conceivably be read to confer this 180-day period on a second or third applicant in some situations"); *see also* 64 Fed. Reg. 42,873, 42,875 (Aug. 6, 1999) ("The statutory language describing which applications are eligible for 180-day generic drug exclusivity is ambiguous."). It was

incentives that existed in 1993 does not warrant review by this Court, especially given that, since 1993, the relevant statutory provisions have been amended. *See infra* at 27-28.

Petitioners assert that, at a minimum, the first settlement would delay the ultimate adjudication of the patent's validity. Pet. 24. The possibility of such delay is irrelevant, however, to whether petitioners have stated a claim under the Sherman Act. Whatever shortcomings petitioners may perceive in the Hatch-Waxman Act's design for fostering patent challenges, petitioners cannot invent a Sherman Act right for themselves to "show the weaknesses of the patent" based on the purported lack of promptness in alternative challenges.

Nor does the supposed trend identified by the FTC in favor of settlements that include consideration to the generic challenger suggest, as petitioners imply, Pet. 15-16, that patent challenges are no longer being litigated to judgment. Statistics showing that such payments have been featured more frequently since 2004, when parties were first required to file agreements settling paragraph IV litigation, say nothing about the number of patent cases being litigated to judgment. And the number of lawsuits resulting in judgments that patents are invalid or unenforceable since *Valley Drug* demonstrates that

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therefore reasonable for the Second Circuit to conclude, in the context of this case, that the subsequent challengers may have been "spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit * * *." Pet. App. 55a-56a. Indeed, even the commentator cited by petitioners has acknowledged that the relevant statutory and regulatory provisions were susceptible to more than one interpretation at the time. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1583 & n.125 (Nov. 2006) (conceding that interpretation that only the first filer was eligible for exclusivity was "not the only plausible interpretation of the relevant statutory provision").

settlements have not foreclosed such outcomes, petitioners' alarmist claims notwithstanding.[12]

In support of review, petitioners also point to the FTC's views on drug patent settlements, Pet. 9, but those views provide no basis for reviewing the decision below. The FTC maintains that the strength of the patent is irrelevant, instead arguing that settlement payments take the place of other consideration that would tend to enhance competition, such as license agreements or agreements to permit entry on a date prior to the expiration of the patent. *See In re Schering-Plough Corp.*, No. 9297, 2003 FTC LEXIS 187, at *60-61, *76-79 (FTC Dec. 8, 2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005) (rejecting FTC's approach), *cert. denied*, 126 S. Ct. 2929 (2006). Petitioners' theory of liability, by contrast, is focused on the purported "weaknesses" in the patent itself. Moreover, the FTC stated in 2003, after the district court's dismissal of petitioners' claims below, that AstraZeneca's success in defending the patent supported the district court's ruling because it indicated that respondents' settlement did not harm consumers:

> "In [*Tamoxifen*], the validity of [AstraZeneca's] patent was the crucial issue in the underlying patent dispute and, subsequent to the settlement in question, [AstraZeneca's] patent was successfully defended in

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[12] Since *Valley Drug*, at least six drug patents challenged pursuant to the Hatch-Waxman Act have been completely or partially invalidated after review by the Federal Circuit, including patents for Paxil and Lipitor. *See Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003); *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364 (Fed. Cir.), *cert. denied*, 126 S. Ct. 488 (2005); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 2887 (2006); *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312 (Fed. Cir. 2006); *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284 (Fed. Cir. 2006), *petition for cert. filed*, 75 U.S.L.W. 3403 (U.S. Jan. 22, 2007) (No. 06-1016); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286 (Fed. Cir. 2006).

> litigation with three other generic challengers. In a private action for damages, after the fact, the *Tamoxifen* [district] court had good reason to believe that the settlement did not ultimately cause consumer harm." *Id.* at *71.

Although the FTC supported petitioners' request for rehearing below, it did not retract its endorsement of the result in this case. Given that endorsement, and that petitioners did not advance below the FTC's theory that settlement payments unlawfully substitute for more procompetitive settlement terms, the FTC's views provide no basis for reviewing the decision below.[13]

## III. THIS CASE IS A POOR VEHICLE FOR DETERMINING WHEN SETTLEMENTS OF DRUG PATENT CLAIMS MAY VIOLATE THE SHERMAN ACT

Several features of this case make it a poor vehicle for considering when a patent settlement may violate the Sherman Act. To the extent that the issues presented by the petition hold any interest, this Court should defer addressing them until presented with an appropriate case.

1. Important aspects of this case are highly unusual and almost certain never to recur. Respondents settled their patent dispute after a district court had first held the patent invalid and unenforceable, and the settlement was conditioned on, and brought about, the vacatur of that judgment. This feature of the settlement, so emphasized by petitioners, *see* Pet. 4, 11, 20-21, 23, is to our knowledge absent from every other drug patent settlement that has been challenged as

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[13] Nor, for that matter, do petitioners point to any case to support the proposition that an otherwise lawful agreement or settlement violates the Sherman Act simply because the agreement did not include other terms that might have been more procompetitive.

anticompetitive. Nor is it likely to be presented in future cases, given that, shortly after the settlement here was reached in 1993, this Court in *U.S. Bancorp Mortgage Co. v. Bonner Mall Partnership*, 513 U.S. 18, 27-29 (1994), ended the practice of vacating judgments in cases settled on appeal.

This case also features the unusual circumstance that, after the initial district court ruling of invalidity was vacated, two other federal district courts (and, in one case, the Federal Circuit) later enforced the tamoxifen patent against two other generic manufacturers. This case-specific sequence of conflicting judgments, although scarcely mentioned by petitioners, was noted repeatedly by the court of appeals. *See* Pet. App. 34a, 55a-57a, 65a-67a. Nor can this pattern recur after *Bonner Mall*. With no means of obtaining vacatur, a patentee whose patent has been declared invalid would be precluded from enforcing the patent against other infringers, *see Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 331 (1971), and thus could never obtain a subsequent judgment that the patent was valid, as occurred in this case. In short, the highly unusual background of this case, which was important to the analysis of the courts below, distinguishes this action from other lawsuits challenging patent settlements. For this reason, it is highly probable that a decision in this case would have only limited application to other cases presenting less extraordinary circumstances.

2. The 180-day exclusivity provisions of the Hatch-Waxman Act that foster challenges to drug patents, which petitioners argue at length that the Second Circuit misconstrued, *see* Pet. 24-27, have been amended and clarified since respondents settled their patent dispute in 1993. (The petition reproduces the current version of the statute, *see* Pet. App. E.) Among other amendments, in 2003, Congress introduced the term "first applicant" into the statute to describe applicants who may be eligible for the 180-day exclusivity period, changed the manner in which exclusivity is triggered

and introduced mechanisms by which exclusivity may be forfeited. *See* 2003 Medicare Act, Pub. L. No. 108-173, § 1102(a), 117 Stat. 2066 (codified at 21 U.S.C. § 355(j)(5)(B)(iv), (j)(5)(D)). Neither the courts nor the FDA have definitively interpreted these new provisions, which could significantly alter the way exclusivity operates when patent litigation is settled. If the exclusivity regime bears on whether respondents' settlement violated the Sherman Act, as petitioners argue, a decision in this case, insofar as based on provisions of law that are no longer in effect, would provide only limited guidance for other cases.

3. Whether petitioners have stated a valid Sherman Act claim is relevant, at this stage of the case, only because the standards necessary for stating a claim under the Sherman Act presumably also govern petitioners' state competition and consumer protection law claims. Petitioners, as indirect purchasers, sought only declaratory and injunctive relief under the Sherman Act. That relief is no longer obtainable, because respondents' agreement terminated in 2002 with the expiration of the '516 patent. *Cf. Standard Oil*, 283 U.S. at 182 (holding that, where "the relief * * * sought is an injunction, and hence relates only to the future * * *, the alleged validity of [canceled] provisions has become moot") (internal citations omitted). Although without jurisdictional import—because petitioners have asserted damages claims under their state law causes of action—this feature of the case provides another prudential basis for denying the petition. Even though petitioners' state law claims are presumably governed by Sherman Act standards, and are necessarily subject to limits imposed by federal patent law, the Court's examination of claims that a settlement of drug patent litigation violated the Sherman Act would most appropriately be conducted in a case presenting a live Sherman Act claim.

## CONCLUSION

For the reasons set forth above, the petition for a writ of certiorari should be denied.

Respectfully submitted,

GEORGE C. LOMBARDI
LINDA T. COBERLY
MAUREEN L. RURKA
KEVIN E. WARNER
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
(312) 558-5600

*Attorneys for Respondent Barr Laboratories, Inc.*

ARTHUR F. GOLDEN
*Counsel of Record*
JOEL M. COHEN
CHARLES S. DUGGAN
DOUGLAS K. YATTER
DAVIS POLK & WARDWELL
450 Lexington Avenue
New York, New York 10017
(212) 450-4388

*Attorneys for Respondents AstraZeneca Pharmaceuticals LP, Zeneca Inc. and AstraZeneca PLC*

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